REMARKS

Claims 1-23 are pending. By this response, claims 1, 17 and 21 are amended. Reconsideration of the present application is respectfully requested.

I. The Claims Are Patentable over the Cited References

The Office Action rejects claims 1-7, 11-14 and 17-23 under 35 U.S.C. §103(a) over U.S. Patent No. 5,955,058 to Jager et al. ("Jager") in view of U.S. Patent No. 6,296,156 to Lasserre et al. ("Lasserre"), and claims 8-10 and 15-16 under 35 U.S.C. §103(a) over Jager and Lasserre, and in further view of U.S. Patent No. 6,149,892 to Britto. The Office Action also provisionally rejects claims 1-16 under the judicially created doctrine of obviousness-type double patenting over copending Application No. 10/290,225 in view of Lasserre, and copending Application No. 10/244,519 in view of Lasserre. These rejections are respectfully traversed.

A. Claims 1-7, 11-14 and 17-23

The applied references do not disclose an active ingredient subject to a degradation, a canister with a rim having rounded edges, and an aerosol solution formulation being in contact with a gasket when in at least one of a use position and a storage position" as recited in claims 1, 17 and 21.

Instead, Jager teaches that medicinal aerosol solution formulations comprising medicaments that degrade or decompose by interaction with solvents or water, an HFC (HFA) propellant and a cosolvent, can be stabilized by addition of an acid. According to Jager the formulations are stable and "exhibit substantial chemical stability over time" (col 2, lines 32-34). The examples of medicaments in Jager do not comprise steroids.

In addition, Lasserre discloses a container 4 having a dispensing valve 2 connected to a dip tube 22. Col. 5, lines 48-50. As such, the device 1 must always be used in an upright

position. Since the device 1 is not used or stored in an inverted position, the product P is not in direct contact with the elastomeric seal 25.

Furthermore, Lasserre does not disclose that the "product inside the container is not exposed to any corrosion, thus resolving the degradation problem," but on the contrary that "valve holder cup may be damaged by the product that is to be dispensed, particularly when this product contains corrosive components" (col 1, lines 60-63). In other words, in Lasserre is the product contained inside the container that can corrode the valve and not materials released by the valve gasket that can impair the chemical stability of the medicament contained inside the canister. Lasserre discloses that the neck of the container may be rolled outwards or inwards, with respect to the axis of the container, only in connection with the problem that the profile of said neck has to engage with a portion of the mounting means (col 4, lines 23-34).

Lasserre in no way discloses or suggests to utilize containers with rolled necks to improve the chemical stability of an active ingredient dissolved in a propellant/cosolvent system.

On the other hand Jager teaches that formulations containing an anticholinergic compound such as ipratropium bromide or a β_2-agonist such as formoterol are stable over time since an acid is present.

The technical problem underlying the present invention is related to the finding that peroxides released from the gasket or other compounds that can leach from the closed system into the formulation affect the chemical stability of certain active ingredients in solution formulations comprising a HFA propellant and a cosolvent. This problem can be worsened by standard MDI canisters having a cutting edge opening. The cutting edge, during the valve crimping phase, may lead to damage and compression of the surface of the rubber, which may

cause breaks or cuts in the rubber gasket and consequently release peroxides and leachables with time in the solution formulation.

Accordingly, the canister in the present invention is provided with a rim having rounded edges which avoids contact of a sharp edge with the gasket. The present invention relates to a canister that is used and/or stored in an inverted position. The problem that is solved by the invention occurs when the aerosol solution formulation is in contact with the gasket. The problem does not occur if the cans are stored upright because the solution is not in direct contact with the gasket. Paragraph [079].

Therefore, there is no reason or hint to combine the teachings of Jager and Lasserre to arrive at the present invention.

B. Claims 8-10 and 15-16

Britto teaches that inner coating of aerosol canisters can reduce or eliminate the problem of drug adhesion or deposition on the can walls and thus ensures consistent delivery of medicament in aerosol form from the MDI where the active ingredient is suspended in the formulation. Therefore, Britto offers a solution to a different problem, i.e. the deposition of a drug in the form of a finely divided powder onto the walls of the can. Britto is completely silent about problems of chemical stability and/or chemical degradation of an active ingredient in solution in a propellant or cosolvent system and on the possibility to enhance its chemical stability by storing the solution composition in a container having part or all of the internal surfaces made of stainless steel, anodized aluminum or lined with an inert organic coating and a rim with rounded edges.

Finally, the Office Action indicates that motivation to produce the claimed invention can be found in the knowledge generally available to one of ordinary skill in the art. Applicants respectfully disagree.

The technical problem underlying the invention was not recognized before the present invention. Thus, there was no incentive for one of ordinary skill in the art to put an aerosol solution formulation containing an active ingredient subject to chemical degradation in a canister having a rim with rounded edges to prevent the contact of a sharp edge with the rubber gasket of the valve.

C. Double Patenting Rejections

For at least the reasons stated above, the obviousness-type double patenting rejections should also be withdrawn. In addition, the Office Action fails to point out which claims of the co-pending applications provide the basis for the rejection. Thus, Applicants respectfully assert that the provisional rejections are also improper for failing to provide a proper basis.

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In sum, Applicants respectfully submit that there is no motivation taught or suggested by the applied references to modify the teachings of Jager with the teachings of Lasserre and/or Britto to obtain the claimed product. Applicants submit that only through hindsight would one be motivated to modify Jager to meet the features of the claims. MPEP §2141, under the heading "Basic Considerations Which Apply to Obviousness Rejections," points out that "the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention." *See Hodosh v. Block Drug Co.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). The Federal Circuit has clearly held that "the motivation to combine

references cannot come from the invention itself." *Heidelberger Druckmaschinen AG v. Hantscho Commercial Prods., Inc.*, 21 F.3d 1068, 30 USPQ2d 1377 (Fed. Cir. 1993).

Accordingly, Applicants respectfully submit that the rejections should be withdrawn.

II. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 1-23 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number set forth below.

Any fees incident to this Amendment may be charged to Deposit Account No. 08-2665.

DATED this 29th day of July, 2005

Respectfully submitted,

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